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510(k) SUMMARY

Submitted By: Perry Guinn, Vice President, Quality Assurance and Regulatory Affairs
Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
(765) 412-6318
September 12, 2006

Name of Device:

Trade Name: SURGISIS® Biodesign™ Enterocutaneous Fistula Plug
Common/Usual Name: Surgical Mesh
Proposed classification name: Surgical Mesh
21 CFR 878.3300 (FTM)
Class II

Predicate Device:

The predicate device is the original SIS Fistula Plug (510(k) No. K050337), cleared for marketing by the Food and Drug Administration on March 9, 2005.

Device Description:

The modified SIS Fistula Plug is manufactured from porcine small intestinal submucosa (SIS) supplied in a tapered configuration with a flange to provide increased retention of the plug and improved blockage of the fistula. The device is packaged in a lyophilized (freeze-dried) state, and supplied sterile in a sealed double pouch system.

Substantial Equivalence:

The modified SIS Fistula Plug is similar with respect to intended use, materials and technological characteristics to the original, unmodified SIS Fistula Plug as shown through an analysis of risk factors, bench testing and biocompatibility testing.

Discussion of Tests and Test Results:

The materials comprising the modified SIS Fistula Plug have been subjected to extensive biocompatibility testing, viral inactivation testing, and mechanical testing. Outcomes show the

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device to be biocompatible, adequately disinfected, and with appropriate mechanical characteristics.

Conclusions Drawn from the Tests:

Outcomes from the evaluation of the modified SIS Fistula Plug provide evidence of its suitability for use in soft tissue reconstruction and substantial equivalency to the predicate device in terms of intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cook Biotech, Inc.
% Med Institute, Inc.
Mr. Perry W. Guinn
VP, QA/RA
1425 Innovation Place
West Lafayette, Indiana 47906

FEB 27 2009

Re: K082682
Trade/Device Name: SURGIS® Biodesign™ Enterocutaneous Fistula Plug
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: February 18, 2009
Received: February 19, 2009

Dear Mr. Guinn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Fed-ral Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson for
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082682

Device Name: SURGISIS® Biodesign™ Enterocutaneous Fistula Plug

Indications for Use: The modified SIS Fistula Plug is indicated for implantation to reinforce soft tissue for repair of enterocutaneous fistulas.

Prescription Use __XX___ AND/OR Over-the-Counter Use_____

(Per 21 CFR 801 Subpart D) (21 CRF 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone for MKM 2/22/2009

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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